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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KARL KOLTER and MAXIMILIAN ANGEL

Appeal 2009-011494
Application 10/501,773
Technology Center 1700

Before BRADLEY R. GARRIS, CHARLES F. WARREN, and
CATHERINE Q. TIMM, *Administrative Patent Judges*.

TIMM, *Administrative Patent Judge*.

DECISION ON APPEAL

I. STATEMENT OF CASE

Appellants appeal under 35 U.S.C. § 134 from the Examiner's decision to reject claims 1, 2, 5, 7, 10, 11, 20, and 27-30. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

Appellants' invention relates to quick dissolving film coatings for coating solid substrates such as pharmaceutical, cosmetic or agrochemical product forms, seed, dietary supplements, and foods (Spec. 1:6-8).

Appellants claim the coating composition (Claim 1), a solid substrate coated with the composition (Claim 27), and the substrate itself (Claim 28). Claim 1 is illustrative of the coating composition:

1. A quick dissolving film coating composition for coating solid substrates, composed of
 - a) 10 - 90% by weight of a polyvinyl alcohol-polyether graft copolymer (component A),
 - b) 5 - 80% by weight of at least one further component containing at least one functional group selected from the group consisting of hydroxyl, amide and ester functions (component B), and
 - c) 0 - 70% by weight of further customary coating constituents (components C).

The Examiner maintains, and Appellants seek review of, the following rejections:

- A. claims 1, 2, 5, 10, 20, 27, and 28 rejected under 35 U.S.C. § 102(b) as anticipated by Gotsche (WO 00/18375, pub. Apr. 6, 2000);¹
- B. claim 7 rejected under 35 U.S.C. § 103(a) as unpatentable over Gotsche in view of Castillo (US 5,091,185; issued Feb. 25, 1992);
- C. claim 11 rejected under 35 U.S.C. § 103(a) as unpatentable over Gotsche in view of Babaian (US 4,842,854; Jun. 27, 1989); and

¹ During prosecution, Appellants relied upon U.S. Patent 6,579,953, which issued to Gotsche et al. on June 17, 2003, as the English language equivalent to WO 00/18375. We cite to and rely upon the U.S. Patent as well.

- D. claims 29 and 30 rejected under 35 U.S.C. § 103(a) as unpatentable over Gotsche.

II. DISCUSSION

A. ANTICIPATION BY GOTSCHKE

With respect to the anticipation rejection over Gotsche, Appellants do not argue any claim apart from the others. We select claim 1 as representative for resolving the issue on appeal for this rejection. The issue is: Does the evidence as a whole support the Examiner's finding that Gotsche describes, within the meaning of 35 U.S.C. § 102, a composition containing both a polyvinyl alcohol – polyether graft copolymer (component A) and a component containing at least one hydroxyl, amide, or ester functional group (component B) as required by claim 1?

We answer this question in the affirmative.

There can be no real issue that Gotsche describes a genus of polymers which are polyvinyl alcohol – polyether graft copolymers within the meaning of claim 1. In fact, Appellants' own Specification admits as much (Spec. 2:4-8). In light of this fact, we are not persuaded by Appellants' argument that the claimed component A is merely described in an enormous genus taught by Gotsche (Br. 4). In fact, component A of claim 1 encompasses an enormous genus, i.e., all polyvinyl – polyether graft copolymers, and Gotsche describes a subgenus within the claimed genus.

Component B of claim 1 encompasses all components containing at least one functional group selected from the group consisting of hydroxyl, amide and ester functions. Appellants' Specification illuminates the breath of this claim language. According to the Specification, component B can

comprise polymers including, for example, polyvinyl alcohols, celluloses, such as hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, hydroxyethylmethylcellulose, methylcellulose, polyethylene glycols, polyethylene glycol-polypropylene glycol block copolymers, polyvinylpyrrolidones, vinylpyrrolidone-vinyl acetate copolymers, vinylpyrrolidone-methacrylate copolymers, vinylpyrrolidone-acrylate copolymers, (meth)acrylate copolymers, vinylpyrrolidone-vinyl acetate copolymer (copolyvidone), as well as many others or even silica (Spec. 5:21 to 6:27). The claimed component B is also a very large genus of components.

There is no dispute that column 12, lines 9-12 of Gotsche describes combining polyvinyl alcohol - polyether graft copolymers with other polymers (Br. 5). Gotsche further states:

Examples of polymers which can be employed for this purpose are the following:

polyvinylpyrrolidone, polyvinylpyrrolidone copolymers, water-soluble cellulose derivatives such as hydroxypropyl-cellulose, hydroxypropylmethylcellulose, methylcellulose, hydroxyethylcellulose, acrylate and methacrylate copolymers, polyvinyl alcohols, polyethylene glycols, polyethylene oxide/polypropylene oxide block copolymers.

(Gotsche, col. 12, ll. 13-21.)

As shown by Appellants' Specification, Gotsche's list of polymers described in column 12 is a subgenus of components "containing at least one functional group selected from the group consisting of hydroxyl, amide and ester functions" as required by claim 1. Therefore, Gotsche describes a composition including a polyvinyl alcohol – polyether graft copolymer

(component A) in combination with other polymers, all of the exemplified polymers being component B constituents within the meaning of claim 1.

The evidence as a whole supports the Examiner's finding that Gotsche describes, within the meaning of 35 U.S.C. § 102, a composition containing both a polyvinyl alcohol – polyether graft copolymer (component A) and the further component containing one of the functional groups required by claim 1 (component B).

Because Appellants cannot overcome an anticipation rejection by showing unexpected results, we decline to address the showing relied upon by Appellants. *See In re Malagari*, 499 F.2d 1297, 1302 (CCPA 1974) (“If the rejection under § 102 is proper, however, appellant cannot overcome it by showing such unexpected results or teaching away in the art, which are relevant only to an obviousness rejection.”).

B. OBVIOUSNESS OF CLAIM 7

The Examiner rejects claim 7 as obvious over Gotsche in view of Castillo. Claim 7 further limits claim 1 to a composition wherein component B is a polyvinyl alcohol having a degree of hydrolysis of between 80 and 99 mol%. The Examiner acknowledges that Gotsche does not describe using a polyvinyl alcohol having the required degree of hydrolysis and turns to Castillo as evidence of the obviousness of using a polyvinyl alcohol meeting the claim limitation (Ans. 4-5).

Appellants contend one of ordinary skill in the art would not have added the component used by Castillo in the film coating of Gotsche, and further the Examiner has overlooked the synergistic effects disclosed in the present Specification (Br. 7-8).

The first issue is: Does the evidence as whole support the Examiners' conclusion that it would have been obvious to one of ordinary skill in the art to have used a polyvinyl alcohol having a degree of hydrolysis between 80 and 99 mol% in the polymer mixture described by Gotsche?

We answer this question in the affirmative.

The object of Gotsche is to provide water-soluble or water-dispersible polymers as coating agents, binders and/or film forming excipients in pharmaceutical products (Gotsche, col. 2, ll. 66 to col. 3, l. 3). According to Gotsche, this object is achieved by the use of a particular polyvinyl alcohol – polyether graft copolymer (Gotsche, col. 3, ll. 4-43). Gotsche describes combining the graft copolymer with “other film formers” and exemplifies polyvinyl alcohols as one of the polymers that can be employed (Gotsche, col. 12, ll. 9-19). Gotsche discusses drug forms such as controlled-release coatings (Gotsche, col. 2, ll. 13-18).

Castillo describes veterinary implants coated with a sustained-release coating (Castillo, col. 1, ll. 5-10). The coating is a polyvinyl alcohol having a degree of hydrolysis greater than about 95% (Castillo, col. 2, ll. 35-45). Castillo explains that “[t]he water sensitivity of [polyvinyl alcohol] PVA, or the rate at which it goes into solution, is controlled primarily by the degree of hydrolysis” (Castillo, col. 5, ll. 29-31). Further, fully hydrolyzed polymers have a high degree of water resistance and dissolve slowly (Castillo, col. 5, ll. 31-32).

The evidence as a whole supports the position of the Examiner. The evidence tends to show that those of ordinary skill in the art understood the effects of hydrolysis on polyvinyl alcohol. Using highly hydrolyzed

polyvinyl alcohol for its known properties in a mixture with the graft copolymer of Gotsche would have been obvious to one of ordinary skill in the art in the absence of unexpected results.

Appellants argue that the Examiner has overlooked the synergistic effects disclosed in the Specification (Br. 8). Thus, the second issue is: Does the evidence support the Examiner's conclusion of obviousness after all the evidence is weighed anew taking into account the evidence Appellants' rely upon to show unexpected results?

Appellants state that the combination leads to enhanced mechanical properties like elongation at break which are higher than the properties of the individual components or their respective proportionate values, which Appellants state is explained at page 7, line 23 to page 9, line 35 of the Specification. Appellants state that the results shown in the second table of page 8 reporting elongation at break after various storage times are especially surprising (Br. 8).

However, Appellants have not addressed the Examiner's determination that the evidence in the Specification is not probative of unexpected results because the comparison is inadequate (Ans. 8). The comparison on page 8 of the Specification is between various mixtures of a specific polyvinyl alcohol – polyethylene glycol with a specific polyvinyl alcohol with an 88 mol% degree of hydrolysis (Spec. 8) as compared to the pure polymers. There is no evidence that an unexpected increase elongation at break will occur with all of the other polymer mixtures encompassed by claim 7. For instance, it is not clear that the effect will occur with polyvinyl

alcohol having a degree of hydrolysis different from the 88 mol% hydrolyzed polymer.

When all the evidence is weighed anew, the evidence supports the Examiner's conclusion of obviousness.

C. OBVIOUSNESS OF CLAIMS 11, 29, AND 30

The Examiner rejects claim 11 as obvious over Gotsche in view of Babaian and rejects claim 29 and 30 as obvious over Gotsche alone. With regard to these rejections, Appellants do not advance any arguments specifically addressing the findings and conclusions of the Examiner beyond what we have addressed above. Therefore, we sustain these rejections for the reasons discussed above.

III. CONCLUSION

On the record before us, we sustain the rejections maintained by the Examiner.

IV. DECISION

The decision of the Examiner is affirmed.

V. TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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